

## REMARKS

### **I. Status of the Application**

Claims 1-33 are pending in the application. New claims 34-56 have been added. Claims 16-26 stand rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter. Claims 1-3, 5, 6, 10, 11, 13, 14 and 27-33 stand rejected under 35 U.S.C. § 102(b) as anticipated by Vincent et al., U.S. Patent No. 5,007,935. Claims 4, 7-9, 12 and 15 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Vincent et al.

Applicant has amended the claims to more clearly define and distinctly characterize Applicant's novel invention. Support for the amendments can be found in the specification and the claims as originally filed. Claim 1 was amended to recite a hollow pin having an inside bone contact surface and an outside bone contact surface. Claim 29 was amended to recite a substantially hollow pin wherein and inside surface and an outside surface of the hollow pin contact bone. Support for the amendments to claims 1 and 29 can be found at least at page 2, lines 1-11 of the specification, where Applicant teaches a "largely hollow pin" having "an engagement surface for the bone both on the inside and the outside" of the hollow pin. Claim 29 was further amended to recite active method steps. Claims 31 and 32 were amended to clarify claim language.

Support for new claims 34-55 can be found, respectively, in claims 1-15 and 27-33 as originally filed. Support for claim 56 can be found in claim 1 as originally filed. Claims 34 and 56 recite a supporting element having a bottom surface that abuts a sawn-off surface of a bone, and a top surface that is substantially parallel to the bottom surface and is substantially flat. Claim 51 recites a supporting element having a top surface that is substantially parallel to the bottom surface and is substantially flat. Support for a supporting element having a bottom surface that abuts against a sawn-off surface of a bone can be found at least in claim 3 as

originally filed and in the specification at least at page 8, lines 26-27, which teaches “supporting element 22 which is substantially flat,” and at page 9, lines 12-13, which teaches that “the supporting element 22 will come to lie flat against the abutment surface 14.” Abutment surface 14 comprises a supporting edge 16 of cortical bone, which encloses a central surface of spongy bone 18 (page 8, lines 7-9). Support for a top surface that is substantially parallel to the bottom surface and is substantially flat can be found at least at Figure 7, which depicts supporting element 22 and shows a top surface that is flat and substantially parallel to the bottom surface. Applicant respectfully submits that Figure 7 was included in the specification as originally filed and was, therefore, in Applicant’s possession at the time of filing. Accordingly, the language of claims 34 and 51 to incorporate limitations set forth in Figure 7 does not constitute new matter. Support for the language “a pin” in claim 34 can be found at least at page 3, lines 24-30 of the specification where Applicant teaches “the fastening element comprises a supporting element and a pin.” The amendments presented herein add no new matter.

Applicant respectfully requests entry and consideration of the foregoing amendments, which are intended to place the case in condition for allowance.

## **II. Claim Objections**

At page 2, paragraph 1 of the instant Office Action, the Examiner has objected to claims 29-33 for not reciting active method steps. In response, Applicant has amended claim 29 to recite active method steps, thus obviating the objection.

### **III. Rejection of Claims 16-26 Under 35 U.S.C. § 101**

At page 2, paragraph 2 of the instant Office Action, claims 16-26 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. The Examiner asserts that claims 16-26 positively recite the combination of the fastening device and bone, and that the claims are considered to claim a human being, which is considered to be non-statutory subject matter.

Applicant respectfully traverses this rejection. Applicant respectfully submits Applicant is not claiming the insertion of a fastening element into a human, but rather Applicant is claiming an *ex vivo* assembly of bone and a fastening element. The assembly is inserted to supplement bone that has been damaged or is missing, e.g., bone loss due to an accident or as a result of radiation therapy. Such an assembly is useful for transplantation procedures wherein a combination of exogenous bone and a fastening element is introduced into a human.

As claims 16-26 do not claim a human, Applicant respectfully requests that the rejection of claims 16-26 under 35 U.S.C. § 101 be reconsidered and withdrawn.

### **IV. Claims 1-15 and 27-33 Are Novel and Non-Obvious Over Vincent et al.**

At page 3, paragraph 1 of the instant Office Action, claims 1-3, 5, 6, 10, 11, 13, 14 and 27-33 stand rejected under 35 U.S.C. § 102(b) as anticipated by Vincent et al., U.S. Patent No. 5,007,935. The Examiner is of the opinion that Vincent et al. discloses a fastening element comprising a support element 11, a largely hollow pin 6 extending from the supporting element, and a screw tensioning and fixing means 8, 15' (see Fig. 2). The Examiner asserts that the supporting element is plate-shaped where it contacts the bone and extends on two sides of the longitudinal axis of the pin; that the pin is at an angle to the main surface of the supporting element; that a coupling element 40 is positioned on the other side from the pin and is angularly offset from the longitudinal axis; that the cross-section of the pin 6 has a multi-angular shape;

and that the surface of the device is treated so as to promote bone ingrowth. The Examiner is also of the opinion that Vincent et al. shows a method comprising subcapitally sawing off a femur 7 and driving the pin into the bone at an angle with respect to the load-bearing surface; that the pin is fixed from a cortical bone to the fastening element remotely from the abutment surface; a template 73 having holes 87 corresponding to the circumference of a pin 81, 83 includes a central opening 82; and that the holes extend in a direction that is parallel to the longitudinal axis of the pin.

At page 4, paragraph 1 of the instant Office Action, claims 4, 7-9, 12 and 15 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Vincent et al. The Examiner is of the opinion that Vincent et al. discloses the claimed invention except for the fixing means comprising a wire element or the fixing means comprising two or more screws. The Examiner asserts that the use of wire elements and/or multiple screws instead of a single screw is a functionally equivalent means of retaining a joint coupling element, known in the art, and that it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute cables and/or multiple screws for a single screw, since doing so involves nothing more than the substitution of functionally equivalent prosthesis retaining means known in the art. The Examiner further asserts that with regard to claims 7-9, it would also would have been obvious to form the pin at an angle less than 125 degrees, between 125 degrees and 145 degrees, or at an angle greater than 145 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The Examiner also asserts that with regard to claim 12, it also would have been obvious to form the device from a shape-memory metal since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Applicant respectfully traverses these rejections based on the amended claims now presented. Applicant's claims recite a fastening element that comprises a supporting element having attached to it a hollow pin, wherein the hollow pin has an inside bone contact surface and an outside bone contact surface (claim 1 and claims depending therefrom) or wherein an inside surface and an outside surface of the hollow pin contact bone (claim 29 and claims depending therefrom). Because Applicant's hollow pin can simply be driven into the bone, the fastening element can be secured without the removal of bone tissue (page 2, lines 1-6). The resulting contact with bone on both inside and outside surfaces of the pin enables Applicant's claimed fastening element to achieve a high degree of stability upon implantation (page 2, lines 6-11). Furthermore, the arrangement of bone both inside and outside the pin allows bone growth to occur around and inside the pin, further stabilizing the fastening element in the bone.

Vincent et al. fails to teach or suggest each and every element of Applicant's claimed invention. Unlike Applicant's fastening element, the element of Vincent et al. does not comprise a supporting member having a hollow pin having an inside bone contact surface, as claimed by Applicant. Instead, Vincent et al. teaches a supporting member 4 having an extension 6 that is inserted into a sleeve 15 (column 4, lines 26-58; Figures 1 and 2). The inside of the extension comprises a threaded axial bore 6'. Vincent et al. teaches introducing a screw bolt 21 into the sleeve and threading the bolt in the threaded bore of the extension. Thus, the inside surface of the extension of Vincent et al. contacts a bolt, not bone. Nowhere does Vincent et al. teach contacting bone to the inside of extension 6.

Furthermore, based on the teachings of Vincent et al., one of skill in the art would not arrive at Applicant's claimed invention. First of all, as discussed above, Vincent et al. does not teach contacting the inner surface of extension 6 with bone. Secondly, based on the teachings of the Vincent reference, bone would not even be available to contact the inner surface of the

extension because Vincent et al. teaches removal of bone prior to insertion of the extension: “the femur 7 is provided with a throughbore 13' along an axis 13 extending at a small acute angle to the natural femur axis...the extension 6 is introduced into the bore 13” (column 4, lines 23-25 and line 50). Accordingly, based on the teachings of Vincent et al., one of skill in the art would not envision a fastening element comprising a hollow pin having an inside bone contact surface, as claimed by Applicant.

As Vincent et al. provides no teaching or suggestion to lead one of ordinary skill to arrive at Applicant's invention, Applicant respectfully requests that the rejections of claims 1-15 and 27-33 under 35 U.S.C. §§ 102(b) and 103(a) be reconsidered and withdrawn.

**V. New Claims 34-56 Are Novel and Non-Obvious Over Vincent et al.**

New claims 34-56 recite a fastening element that comprises a supporting element that has a bottom surface that abuts a sawn-off or abutment surface of a bone, and a top surface that is substantially parallel to the bottom surface and is substantially flat. Applicant's claimed supporting element is designed to lie against a sawn-off cross-section of bone, thus giving the fastening element advantageous force transmission into the long portion of the femur (page 2, line 24 to page 3, line 2). This arrangement of the supporting element on the bone provides a normal angle between the longitudinal axis of the femur and the longitudinal axis of the neck (page 3, lines 9-12), which allows normally occurring pressure forces on the supporting element into the femur such that no or only minimal moments occur, which leads to increased stability of the implant (page 5, lines 3-9 and page 3, line 24 to page 4, line 4). In addition, the flat characteristic of Applicant's supporting element necessitates removal of only a small portion of the femur when used as an implant.

Vincent et al. fails to teach or suggest each and every element of Applicant's claimed invention. Unlike Applicant's fastening element, the element of Vincent et al. does not comprise a supporting member having a bottom surface and a top surface that is substantially parallel to the bottom surface and is substantially *flat*. Instead, Vincent et al. teaches a supporting member 4 that includes two supporting surfaces 10 and 11 that are oriented in a right angle to one another (column 4, lines 26-42 and Figure 2). The surface opposite the supporting surfaces is rounded, not flat as claimed by Applicant. Thus, the supporting element taught by Vincent et al. is structurally different from Applicant's claimed supporting element.

When Applicant's claimed substantially flat supporting element is used in a hip implant, only a very small amount of bone need be removed. Figures 1B and 1C depict that only the femur head and a portion of the femur neck need be removed during fastening element implantation. Minimal bone removal is advantageous because bone tissue is still available for the addition of replacement implants in later years. In contrast to Applicant's claimed supporting element, the fastening element of Vincent et al. comprises a "**block**-like supporting member" (4, 41) (abstract, emphasis added) which, when used as an implant, necessitates removal of a far larger portion of the femur than one would need to remove to use Applicant's fastening element. Figure 2 of Vincent et al. depicts that all of the head and neck and part of the femur have been removed to accommodate the fastening element.

Furthermore, when used as an implant, the fastening element of Vincent et al. would not apply the same forces and resultant moment as Applicant's fastening implant. As the transmission of forces and moments by the fastening element plays an important role in stress shielding (page 1, lines 20-23; stress shielding is a term of art which refers to the loss of bone that occurs adjacent to a prosthesis), alteration of forces and moment would likely affect the efficacy of the fastening element on bone healing. The supporting surfaces 10 and 11 of the

supporting element taught by Vincent et al. contact surfaces 7' and 7" of a femur, which are arranged at right angles to one another (column 4, lines 43-45 and Figure 2). Thus, the fastening element of Vincent et al. would transmit force perpendicular to the long portion of the femur as well as down into the long portion of the femur which would, accordingly, affect the moment of the force. In contrast, Applicant's supporting surface transmits force down into the long portion of the femur.

As Vincent et al. provides no teaching or suggestion to lead one of ordinary skill in the art to arrive at Applicant's invention, Applicant respectfully submits that new claims 34-56 are novel and non-obvious over Vincent et al.

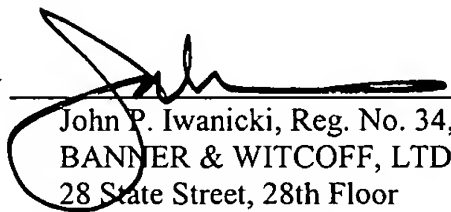
#### VI. Conclusion

Having responded to all outstanding issues, reconsideration and allowance of the pending claims is respectfully requested. If a telephone conversation with Applicants' attorney would expedite prosecution of the above-referenced application, the Examiner is urged to call the undersigned at (617) 720-9600.

Respectfully submitted,

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By

  
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